

### **REMARKS**

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

#### **I. EXAMINER AMENDMENT**

Applicants are grateful for the telephone interview held March 22, 2005 with thank Examiner Belyavskiy, wherein proposed amendments were discussed.

Applicants proposed amending the claims to cancel the recitation "does not substantially recognize" and to include specific dissociation constants for the claimed antibodies. It was noted that such dissociation constants exclude the prior art antibodies, which recognize both active and inactive HGFA as evidenced by the prior Rule 132 Declarations. It was indicated that the proposed amendments appear to place the claims in condition for allowance. The claims have been amended accordingly.

#### **II. CLAIM STATUS**

Claims 1-33 were pending in this application when last examined.

Claim 1-5, 7, 9, 10, 23, 24, 26-28 and 31-33 stand rejected.

Claims 6 and 26-28 were objected to.

Claims 8, 11-22, 25, 29 and 30 have been withdrawn as non-elected subject matter.

Claim 8 was amended to be directed to the elected invention (i.e., now depends on claim 7). Accordingly, it is respectfully requested that claim 8 be included in the elected and examined invention.

Claims 1, 4, 7, 8, 23, 24-28 and 33 have been amended to delete "does not substantially recognize" and to recite specific dissociation constants of  $1 \times 10^{-5}$  M or higher for an inactive HGFA and  $1 \times 10^{-8}$  M or lower for active HGFA. Support for the specific dissociation constants can be found in the specification, for example, at page 27, lines 19-26.

Claims 25-28 have been amended to depend upon the elected claimed invention.

Therefore, no new matter has been added by this amendment.

Claims 31-32 have been cancelled without prejudice or disclaimer thereto. Applicants reserve the right to file a continuation or divisional application on any cancelled subject matter.

Claims 1-30 and 33 are now pending in this application.

### **III. REJECTION UNDER 35 U.S.C. § 102**

Claims 1-5, 7, 9, 31 and 32 were rejected under 35 U.S.C. § 102(b) as anticipated by Shimomura, EP 0 596 524 as evidenced by Goldsby, IMMUNOLOGY, 5<sup>th</sup> ed., pp. 137-139 (2000). See item 5 on pages 2-3 of the Office Action.

It is respectfully submitted that the present amendment overcomes this rejection for the following reasons.

To anticipate a claim, a cited prior art reference must either expressly or inherently teach each and every element of the claimed invention.

The claims call for an antibody that recognizes active HGFA and has a dissociation constant of  $1 \times 10^{-5}$  M or higher for inactive HGFA and a dissociation constant of  $1 \times 10^{-8}$  M or lower for active HGFA. Such amendment excludes the prior art antibodies, because Shimomura EP '524 fails to disclose an antibody with such properties.

In fact, Shimomura EP '524 discloses antibodies that are fundamentally different and distinct from those of the amended claimed invention as evidenced by the Shimomura Declaration and the Naka Declaration submitted with the response filed September 3, 2004. These declarations clearly demonstrate that the prior art antibodies showed equivalent reactivities to both the active HGFA and inactive HGFA. In contrast, the antibodies of the present invention have different reactivities to active HGFA and inactive HGFA. In particular, the amended claimed invention calls for different dissociation constants for active HGFA and inactive HGFA. As such, the antibodies of the present invention recognize active HGFA, but not inactive HGFA. Thus, the declarations clearly demonstrate that the prior art antibodies are fundamentally different and distinct from the antibodies of the present invention.

Therefore, in view of the above, the rejection of claims 1-5, 7, 9, 10 and 31-32 under 35 U.S.C. § 102(b) is untenable and should be withdrawn.

#### **IV. REJECTION UNDER 35 U.S.C. § 103**

Claims 23, 24 and 26-28 were rejected under 35 U.S.C. § 103(a) as obvious over Shimomura EP '524 in view of Zuk, U.S. Patent No. 4,281,061. See item 7 on pages 4-5.

This rejection is respectfully traversed for the same reason set forth immediately above and for the reasons discussed below.

To establish obviousness, three criteria must be met. First, the prior art references must teach or suggest each and every element of the claimed invention. Second, there must be some suggestion or motivation in the references to either modify or combine the reference teachings to arrive at the claimed invention. Third, the prior art must provide a reasonable expectation of success.

In this case, the cited references fail to disclose or suggest antibodies with the dissociation constants of the present invention.

The rejection relies solely upon the primary reference of Shimomura EP '524 for disclosing antibodies that recognize HGFA. However, as discussed above, Shimomura EP '524 discloses antibodies with different and distinct properties from the claimed antibodies. Again, as discussed above, Shimomura EP '524 fails to disclose and/or suggest antibodies with the claimed dissociation constants.

Zuk fails to remedy this deficiency, because this reference is silent as to antibodies reactive to HGFA.

Thus, in view of the above, the cited references fail to disclose and/or suggest each and every element of the claimed invention.

Therefore, the rejection of claims 23, 24 and 26-28 under 35 U.S.C. § 103(a) is untenable and should be withdrawn.

**V. REJECTION UNDER 35 USC § 112, SECOND PARAGRAPH**

Claims 1-7, 9-10, 23-24, 26-28 and 31-33 were rejected under 35 USC § 112, second paragraph, as indefinite for the recitation “does not substantially recognize” inactive HGFA. See item 9 on page 5.

It is respectfully submitted that the present amendment cancelling this language obviates this rejection.

**VI. REJECTIONS UNDER 35 USC § 112, FIRST PARAGRAPH, WRITTEN DESCRIPTION**

Claims 31 and 32 were rejected in 35 USC § 112, first paragraph, on the basis that these claims add new matter lacking written description support.

Claim 32 was also rejected under 35 USC § 112, first paragraph, for a lack of written description support for the genus of antibodies that recognizes the same epitope as the antibody produced by FERM BP-7779. See item 12 on pages 6-7.

It is respectfully submitted that the present amendment cancelling these claims overcomes these rejections.

**VII. OBJECTIONS TO THE CLAIM**

Claim 6 was objected as depending on rejected base claim 1, but would be allowable if rewritten in independent form including all the limitations of the base claim. See item 14 on page 7.

It is respectfully submitted that the above amendments and arguments obviate the rejection of claim 1. Thus, the objection to claim 6 is no longer tenable and should be withdrawn.

Claims 26-28 were also objected to as depending upon non-elected claim 25.

Claim 25 has been amended to be directed to the elected invention. Thus, this objection is untenable and should be withdrawn.

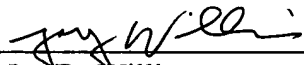
**CONCLUSION**

In view of the foregoing remarks, Applicants submit that the present application is in condition for allowance and notice to that effect is hereby requested.

If it is determined that the application is not in condition for allowance, the Examiner is invited to telephone the undersigned attorney at the number below to expedite prosecution of the present application.

Respectfully submitted,

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